Kaczmarek, Chris

From:

Taub, Cynthia <CTaub@steptoe.com>

Sent:

Wednesday, July 02, 2014 4:35 PM

To:

Talbert, Stephanie (ENRD)

Cc:

Allison_Starmann@americanchemistry.com; Goldberg, Seth; Kaczmarek, Chris; Ross,

Philip

Subject:

Settlement Confidential: 158W

Settlement Confidential

Stephanie:

Thank you for your patience as we worked with our client to find an acceptable path forward towards settlement.

We understand EPA's position on the fungicide and potable water rinse issues is as follows:

- EPA does not intend to change the definition of "fungicide" in the regulation, but is willing to add that issue to the list of issues to be addressed by guidance after the settlement. The guidance would confirm that the definition is limited in application to that subsection, and therefore relates only to the data requirements (i.e., for which products efficacy data is required).
- EPA has taken the position that the potable water rinse issue is not part of 158W and therefore will
 not be part of the settlement. However, EPA is willing to include that as one of issues to be
 addressed by a guidance document outside the settlement.

ACC will agree to the above approach, as long as ACC and its members can immediately discuss the potable water rinse issue with AD, along with the tolerance and incidental oral RA issues that we previously discussed, and EPA agrees to provide a comment period for future versions of the USI. In this way, ACC would be able to open communications with AD on the interconnected issues of tolerances, incidental oral RAs, and the potable water rinse issue (all of which EPA counsel has said are outside of the scope of 158W). In addition, as described in my prior email, the Panel believes that the USI is an important document that will provide substantive guidance on the applicability of the 158W data requirements, and therefore believe any substantive changes to the document should be achieved through notice and comment so that all parties have a chance to comment on future updates. The comment period would allow interested parties to provide additional information that the Agency may not otherwise be aware of that could help inform a particular classification or change. We therefore think the comment period would be beneficial to the Agency, as well as registrants.

We believe this a workable compromise that will narrow the issues involved in the settlement, hopefully allowing for an expeditious resolution.

We look forward to your response.

Cynthia

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